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09/997,829	11/29/2001	Donald T. Shannon	VAS-5041CIP2	5289

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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

MAILED
JUL 06 2006
Group 3700

Application Number: 09/997,829
Filing Date: November 29, 2001
Appellant(s): SHANNON, DONALD T.

Guy Cumberbatch
For Appellant

EXAMINER'S ANSWER

This is in response to the remand of 06/16/06

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of claimed subject matter

The summary of invention contained in the brief is correct.

(6) Grounds of rejection to be reviewed on appeal

The appellant's statement of the grounds of rejections in the brief is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,131,648	***Choi et al.***	***12-1978***
5,700,285	***Myers et al.***	***12-1997***
6,053,940	***Wijay***	***4-2000***
6,287,285	***Michal et al.***	***9-2001***
6,117,165	***Becker***	***9-2000***
5,749,880	***Banas et al.***	***5-1998***

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 103-105,107,113-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. (5700285) in view of Choi et al. (4131648). Myers et al. disclose a stent (Fig. 1) having a plurality of lateral openings. Myers also discloses to place an outer tubular layer of at least one overlapping PTFE tape layer about the stent surface, col. 3, lines 56,57, col. 5, lines 35,44-49 and to sinter the tape, col. 5, lines 59-62. Regarding claim 113, Myers discloses a thickness for the tape less than 0.015 inches, col. 8, lines 3,4. With respect to claims 115,116, Myers also discloses a self-expanding stent, col. 3, lines 39,40 and a shape memory alloy, col. 4, lines 51-54. Regarding claim 117, Myers additionally discloses that PTFE layers can be placed in the stent as a base graft or luminal graft, col. 3, lines 56-59. However, Myers et al. fail to

disclose a polymer incorporated with a therapeutic substance disposed on the surface of the stent. Choi et al. teach a polymer coating that is erodible and comprises a therapeutic agent, col. 2, lines 64-68. Choi also teaches that implantable tubular devices can be coated or layered with the polymer, col. 28, lines 6-8,15-22. Choi additionally teaches that polymer is useful in aqueous environments, col. 28, lines 50-57,67,68. It would have been obvious to one of ordinary skill in the art to use the coating of a bioerodible polymer with a therapeutic agent as taught by Choi et al. on the surface of the stent of Myers et al. such that a drug can be administered to the implantation site where trauma occurred, such as an anti-inflammatory, see col. 29 of Choi. It would be advantageous to incorporate the therapeutic polymer of Choi with the Myers stent-graft since the Choi polymer is capable of use in aqueous environments, i.e. a blood vessel, thus enabling the delivery of therapeutic drugs and reduce healing time. With respect to claim 105, it should be noted that Choi et al. teach that erosion rates of the polymer can be at a rate of 1μ/hr (col. 36). It would have been an obvious matter of design choice to modify the erosion rate of the polymer, since applicant has not disclosed that using any specific erosion rate provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the erosion rate taught by Choi et al. or the claimed 2μ/hr in claim(s) 105 because both erosion rates for the polymers perform the same function of providing a controlled release rate of the therapeutic agent.

Claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 103 above, and further in view of Michal et al. (6287285). Myers in view of Choi is explained above. However, Myers as modified by Choi fail to disclose the drug paclitaxel to be used on the stent. Michal et al. teach therapeutic agents, such as paclitaxel are used in the invention, col. 4, lines 1,2,9. Michal also teaches that the coating with the drug can be on a metal stent surface, col. 5, lines 34-44. It would have been obvious to one of ordinary skill in the art to use the drug paclitaxel as taught by Michal et al. in the stent of Myers et al. as modified by Choi et al. in order to reduce restenosis.

Claims 108-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 103 above, and further in view of Wijay (6053940). Myers in view of Choi is explained above. However, Myers as modified by Choi fail to disclose a non-foreshortening stent. Wijay teaches a stent having a plurality of undulating elements with at least one linear connector, Fig. 1. Wijay also teaches that the design of the stent allows the length to remain substantially constant in the deployed state, col. 9, lines 48-55. It would have been obvious to one of ordinary skill in the art to use the stent design as taught by Wijay in the stent of Myers et al. as modified by Choi et al. in order to provide the maximum support to the vessel and reduce twisting and unwanted turbulence of blood flow.

Claims 108-110,112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 103 above, and further in view of Becker (6117165). Myers in view of Choi is explained above.

However, Myers as modified by Choi fail to disclose a non-foreshortening stent. Becker teaches a stent having a plurality of undulating elements with at least one connector, Fig. 6. Becker also teaches that the design of the stent allows the length to remain substantially constant in the deployed state, col. 4, lines 1-10. It would have been obvious to one of ordinary skill in the art to use the stent design as taught by Becker in the stent of Myers et al. as modified by Choi et al. in order to provide the maximum support to the vessel and increasing the effective range of the stent.

Claims 118,119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285 in view of Choi et al. '648 as applied to claim 117 above, and further in view of Banas et al. (5749880). Myers in view of Choi is explained above. However, Myers as modified by Choi fail to PTFE particles used to bond the tubular inner and outer layers. Banas et al teach an aqueous polymer solution of PTFE between the inner graft and outer graft layer to bond the layers, col. 10, lines 4-8. Bans also teaches the outer tubular layer is heated to bond to the base, col. 20, lines 41-45. It would have been obvious to one of ordinary skill in the art to substitute the adhesive material and use PTFE particles (in solution) as taught by Banas in the stent of Myers et al. as modified by Choi et al. in order to provide a good bond so the layers do not separate in the vessel. Using like materials enhances the bond as opposed to the adhesive material used by Myers using dissimilar material to bond the layers.

(10) Response to Argument

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Choi '648 provides a motivation in that devices and **coatings** can be used with drugs to deliver at a controlled rate and the delivery polymer is biodegradable, col. 2, lines 63-68. Applicant's arguments state that Choi does not teach a coating *on a stent or graft*. Even though that may be evident, *In re Dembiczak* 175 F.3d at 999, 50 USPQ2d at 1617 suggest that a reference *need not expressly teach* that the disclosure contained therein should be combined with another, but a showing must be "clear and particular." In this case, first it should be pointed out that stent-grafts are used in vessels, which permit the flow of fluid, whether it is blood, urine or even bile. Choi teaches that the polymer coatings containing drugs are used in aqueous or "fluid" environments (col. 28, lines 61-68) and that the device the polymer is used with can permit the drugs to be transported across a vessel, col. 29, lines 24-29. It is well known to one of ordinary skill in the art that blood vessels, ureter, urethra or bile ducts all carry fluid that would be considered an aqueous environment and that stent-grafts are often used to hold open and support these vessels when they are blocked, clogged or have a reduced flow rate. Someone of

ordinary skill in the art would also know what a coating is and would look to the coating art to provide a delivery vehicle for drugs. Therefore, the motivation can be implicit from the prior art as a whole, rather than expressly stated in the references and Choi clearly implies blood vessels can be one possible treatment site in which a device, i.e. stent-graft is used to correct for failure of blood flow. See *In re Kotzab* 217 3d 1365,1370, 55 USPQ2d 1313,1317 (Fed. Cir. 2000). The test for an implicit showing is what the combined teaching, knowledge of one of ordinary skill in the art; and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art. In conclusion, to provide a *drug* delivering device is an obvious expedient to one of ordinary skill in the art and one of ordinary skill in the art would look for ways to accomplish that. Using a drug containing coating clearly accomplishes that objective.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

TC 3700, AU 3738
Primary Examiner
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December 15, 2005

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